

SEP 06 2007

Attorney Docket No.: BVTP-P01-539

U.S.S.N. 09/453,109

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

1. (Canceled)
2. (Currently Amended) The device of claim [[1]] 48, further comprising a means for inducing transport of a biological fluid or component thereof into the collection chamber.
3. (Original) The device of claim 2 wherein the pressure within the collection chamber can selectively be reduced.
4. (Original) The device of claim 3 wherein the pressure reduction is induced by expanding the internal volume of the collection chamber.
5. (Original) The device of claim 4 wherein the collection chamber is a standard or Luer-lock syringe.
6. (Original) The device of claim 3 wherein the collection chamber comprises an upper portion which is formed of a material which is deformable.
7. (Previously Presented) The device of claim 3 wherein the means for inducing transport comprises a plunger movably secured to the substrate, wherein the plunger can deform the collection chamber.
8. (Previously Presented) The device of claim 6 wherein the collection chamber comprises a one-way valve.
9. (Canceled)
10. (Currently Amended) The device of claim [[1]] 48, comprising a three dimensional array of microneedles.
11. (Currently Amended) The device of claim [[1]] 48, further comprising an adhesive material for securing the device to a biological barrier surface during fluid withdrawal or sensing.
12. (Currently Amended) The device of claim [[1]] 48, further comprising a means for controlling flow through the microneedle.
13. (Original) The device of claim 12 wherein the means for controlling flow is a fracturable or removable barrier which is interposed between the collection chamber and base of the microneedle.

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14. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, further comprising a sensor in communication with the collection chamber.
15. **(Canceled)**
16. **(Currently Amended)** The device of claim ~~[[15]]~~ 54, wherein the sensor comprises:  
a chemical or biochemical agent that react with the analyte, and  
electrochemical or optical transducers which measure the reaction of the agent and the analyte.
17. **(Previously Presented)** The device of claim 16 wherein the agent is an enzyme selected from the group consisting of glucose oxidase, glucose dehydrogenase, and combinations thereof.
18. **(Currently Amended)** The device of claim ~~[[15]]~~ 54, further comprising an electronics package in communication with the sensor.
- 19-20. **(Canceled)**
21. **(Currently Amended)** The device of claim ~~[[20]]~~ 55, wherein the sensor comprises:  
a chemical or biochemical agent that reacts with the analyte, and  
electrochemical or optical transducers which measure the reaction of the agent and the analyte.
22. **(Currently Amended)** The device of claim ~~[[20]]~~ 55, further comprising an electronics package in communication with the sensor.
23. **(Canceled)**
24. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the collection chamber is adapted to receive and use glucose strips.
25. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the microneedle is hollow and comprises at least one opening in the side of the microneedle.
26. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the microneedle has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into the collection chamber.
27. **(Currently Amended)** A method for collecting a sample of a biological fluid or analyte therein, comprising the steps:  
providing the device of ~~[[claim 2]]~~ any one of claims 47-51;

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inserting said one or more microneedles of the device into a biological barrier comprising biological fluid; and

triggering the means for inducing to permit the transport of a quantity of the biological fluid or analyte therein through said one or more microneedles and into the collection chamber.

28. **(Currently Amended)** The method of claim 27, wherein triggering the transport is effected by the means for inducing is selected from the group consisting of capillary action, diffusion, mechanical pumps, electroosmosis, electrophoresis, convection, or [[and]] combinations thereof.
29. **(Currently Amended)** The method of claim 27, wherein triggering the transport is effected by the means for inducing utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.
30. **(Original)** The method of claim 27 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.
31. **(Currently Amended)** A method for sensing an analyte in a biological fluid, comprising the steps:
- providing the device of claim [[15]] 52, 54, or 55;
  - inserting said one or more microneedles into a biological barrier comprising said biological fluid which contains said analyte; and
  - contacting the sensor with the biological fluid, thereby sensing the analyte.
32. **(Previously Presented)** The method of claim 31 wherein the device further comprises:
- at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and
  - a means for inducing transport of the biological fluid or the analyte therein into the collection chamber,
  - wherein, after the microneedles are inserted, the means for inducing is triggered to draw the biological fluid or the analyte therein through the microneedles and into the collection chamber.

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33. **(Previously Presented)** The method of claim 32 wherein the means for inducing utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.
34. **(Original)** The method of claim 33 wherein the pressure gradient is created by increasing the volume within the collection chamber.
35. **(Original)** The method of claim 31 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.
36. **(Currently Amended)** The method of claim 27, wherein the analyte is glucose, and for sensing glucose wherein the biological barrier is human skin.
37. **(Currently Amended)** The method of claim 31, wherein the analyte is glucose, and for sensing glucose wherein the biological barrier is human skin.
38. **(Canceled)**
39. **(Currently Amended)** The device of claim ~~[[38]]~~ 51, wherein the microneedle consists essentially of a metal.
40. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the microneedle is hollow.
41. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the microneedle is perpendicular to a surface of the substrate.
42. **(Currently Amended)** The device of claim ~~[[15]]~~ 54, wherein the microneedle comprises a metal.
43. **(Previously Presented)** The device of claim 42, wherein the microneedle consists essentially of a metal.
44. **(Currently Amended)** The device of claim ~~[[15]]~~ 54, wherein the microneedle is hollow.
45. **(Currently Amended)** The device of claim ~~[[15]]~~ 54, wherein the microneedle is perpendicular to a surface of the substrate.
46. **(Currently Amended)** The device of claim ~~[[1]]~~ 48, wherein the microneedle has a diameter between about 40 and 120  $\mu\text{m}$ .
47. **(Previously Presented)** A device for collecting a sample of a biological fluid comprising:

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one or more hollow or porous microneedles, each having a base end and a tip;  
a substrate to which the base end is attached or integrated; and  
at least one collection chamber suitable for collecting said sample of said biological fluid, said collection chamber selectably in fluid communication with the base end, and wherein said collection chamber comprises a one-way valve and an upper portion which is formed of a deformable material.

48. **(Previously Presented)** A device for collecting a sample of a biological fluid comprising:

one or more hollow or porous microneedles, each having a base end and a tip;  
a substrate to which the base end is attached or integrated; and  
at least one collection chamber suitable for collecting said sample of said biological fluid, wherein said collection chamber is selectably in fluid communication with the base end, and comprises a plurality of compartments.

49. **(Previously Presented)** A device for collecting a sample of a biological fluid comprising:

one or more hollow or porous microneedles, each having a base end and a tip;  
a substrate to which the base end is attached or integrated;  
at least one collection chamber suitable for collecting said sample of said biological fluid, said collection chamber selectably in fluid communication with the base end; and  
a fracturable or removable barrier for controlling flow through the microneedle, said barrier interposed between the collection chamber and base of the microneedle.

50. **(Previously Presented)** A device for collecting a sample of a biological fluid comprising:

one or more hollow or porous microneedles, each having a base end and a tip;  
a substrate to which the base end is attached or integrated; and  
at least one collection chamber suitable for collecting said sample of said biological fluid, said collection chamber selectably in fluid communication with the base end,

wherein the one or more microneedles has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into the collection

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chamber.

51. **(Previously Presented)** A device for collecting a sample of a biological fluid comprising:

one or more hollow or porous microneedles, each having a base end and a tip, a length between 500  $\mu\text{m}$  and 1 mm and a width between about 1  $\mu\text{m}$  and 500  $\mu\text{m}$ , and comprising a metal;

a substrate to which the base end is attached or integrated; and

at least one collection chamber suitable for collecting said sample of said biological fluid, said collection chamber selectably in fluid communication with the base end.

52. **(Previously Presented)** A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip, a length between about 500  $\mu\text{m}$  and 1 mm and a width between about 1  $\mu\text{m}$  and 500  $\mu\text{m}$ , and comprising a metal;

a substrate to which the base of the microneedle is attached or integrated; and

at least one sensor which is selectably in fluid communication with the microneedle.

53. **(Previously Presented)** The device of any one of claims 47-50, wherein the one or more microneedles each has a length between about 500  $\mu\text{m}$  and 1 mm and a width between about 1  $\mu\text{m}$  and 500  $\mu\text{m}$ .

54. **(Previously Presented)** A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip;

a substrate to which the base of the microneedle is attached or integrated; and

at least one sensor which is selectably in fluid communication with the microneedle,

wherein the one or more microneedles has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into a collection chamber.

55. **(Previously Presented)** A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip; and

a substrate to which the base of the microneedle is attached or integrated;

wherein at least one of the microneedles is or comprises a sensor, and wherein the one or

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more microneedles has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into a collection chamber.

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